

**DENTAL SCHOOL RESEARCH ETHICS COMMITTEE
PROCEDURES
PARTICIPANTS, HUMAN MATERIAL OR HUMAN DATA WITHIN
THE SCHOOL OF DENTISTRY AT CARDIFF UNIVERSITY**

1. Purpose of the Dental School Research Ethics Committee (DSREC)

- 1.1. The Ethics Policy requires that all Research involving human participants, human material or human data (Human Research) be subject to ethical review **before** the Research commences.
- 1.2. The DSREC is primarily responsible for reviewing applications for ethical review for all Human Research proposed by Researchers (staff or students) within the School unless ethical review falls within the remit of an external ethics committee or a specific exemption applies.
- 1.3. Where another university or research institution has conducted ethical review of a research project involving Researchers at Cardiff University, the DSREC is not required to conduct its own ethical review of the research project, but may choose to do so, where appropriate. In all cases where another university or research institution has conducted ethical review of a research project, the DSREC must obtain evidence of the review (namely the outcome letter/communication and relevant ethical review policy) from the Researcher. The DSREC must keep a record of this.
- 1.4. DSRECs are not mandated to review 'Service Evaluation' and/or 'Audit' Activities, as defined in the Ethics Policy, but may choose to do so.
- 1.5. The DSREC is a sub-committee of the University Research Integrity and Ethics Committee (URIEC) and is accountable to URIEC. The role of the DSREC is to operate in accordance with its Terms of Reference, the Ethics Policy and these Procedures.
- 1.6 **Whilst Research falling outside of the definition of 'Human Research' does not require formal ethical review, the Research may still raise ethical issues and Researchers are expected to give these issues due consideration.**

2. Terms of Reference

The DSREC is responsible for:

- 2.1. considering Human Research proposals (from the School's staff and students), where responsibility to conduct ethics review does not fall to an external ethics committee (for example an NHS Research Ethics Committee). This includes all Human Research proposals, regardless of whether the Research is funded;
- 2.2. providing an ethical opinion on the proposal, and a written explanation for the opinion (via a response letter), to the Chief/Principal Investigator;
- 2.3. considering research project amendments;
- 2.4. recording all submitted applications, reviews and committee decisions, including the date the ethical approval was given and the anticipated research project completion date;
- 2.5. monitoring all studies that receive a favourable opinion. Ongoing monitoring and support should be proportionate to the nature and degree of risk and harm involved with the research;
- 2.6. referring cases which cannot be satisfactorily resolved, or about which there is uncertainty, to URIEC;

- 2.7. operating procedures no less rigorous than those suggested or required by relevant professional bodies or other organisations in the subject domain (e.g. Sponsoring/funding bodies);
- 2.8. informing URIEC of any changes in the ethical codes of professional bodies in relevant discipline areas, in order that the University's procedures remain valid;
- 2.9. providing annual reports to the School Board (or equivalent) and to URIEC; and
- 2.10. conducting a review of its procedures at least every three years.

3. Membership and Quoracy

- 3.1. The DSREC will comprise of at least:
 - 3.1.1. a Chair;
 - 3.1.2. Six Academic Members *[the number of Academic Members should be proportionate to the number of proposals requiring review, and meet the requirements of relevant professional bodies, research funders or other organisations in the subject domain];*
 - 3.1.3. one Member from another School; and
 - 3.1.4. one Member from outside of the University (i.e. a lay member).
- 3.2. The School has appointed a School Ethics Officer who will act in accordance with the role description contained in the Ethics Policy and will normally act as Chair of the DSREC.
- 3.3. All DSREC Members will be appointed by the Head of School, assisted by the School Ethics Officer.
- 3.4. The DSREC is quorate when at least one third of the individuals comprising the DSREC are 'in attendance' (meaning either attending in person, via a live electronic link e.g. Skype or via the issuing of comments prior to the meeting) including the Chair and at least one external/lay Member. Quoracy requirements will remain regardless of meeting format. If the DSREC is reviewing an application for ethical review electronically, sufficient Members must respond to ensure quoracy; a nil response will not be considered a favourable opinion.
- 3.5. It is normally expected that the DSREC will reach a consensus in its decision-making. Where disagreement remains, decisions of the DSREC will be made by a majority vote, with the Chair having a casting vote, and this should be recorded in the minutes of the meeting.
- 3.6. Where specific or additional expertise is required to enable the DSREC to review an application for ethical review, it may invite individuals with such expertise (an Expert Advisor) to assist with its review. The role of the Expert Advisor will be to provide guidance and assistance to the DSREC to enable it to make a decision on the application.

4. List of current DSREC Members

| | |
|-------------------|--|
| Chair | Professor V Sivarajasingam |
| Vice Chair | Dr I Johnson |
| | Dr C Emanuel |
| | Dr K Hill |
| | Dr D Farnell |
| | Mr M Langley |
| | Dr A Sydor (<i>external to school rep</i>) |
| | Dr Xiaoqing Wei |

Dr Fiona Morgan (*lay member*)
SECRETARY Mrs B Jones

5. Training for DSREC Members

- 5.1. All DSREC Members must have adequate training, to enable them to carry out their duties. The DSREC will utilise current Cardiff University training courses, where these are available, including:
 - 5.1.1. Research Integrity Online Training Programme;
 - 5.1.2. Research Ethics 1 – Research Governance (online module);
 - 5.1.3. Research Ethics 2 – Working with Human Subjects (online module);
 - 5.1.4. Human Tissue Act (HTA) (online module);
 - 5.1.5. Managing Research Data – Key Aspects of Legal Compliance and Records Management;
 - 5.1.6. Safeguarding Training for Researchers (Child and Vulnerable Adult Protection);
and
 - 5.1.7. Prevent training.

6. Declaration of Conflicts of Interest

- 6.1. The DSREC will ensure that all applications for ethical review are subject to impartial and independent scrutiny, to the extent possible. As such, all DSREC Members are expected to declare any actual, or perceived, conflicts of interest prior to participating in the review of the application. For the purposes of this section, 'conflicts of interest' include any direct or indirect pecuniary or other interest in the Research that could be perceived to influence a Member's judgment.
- 6.2. Any DSREC Member directly involved in the Research submitted for review (whether conducting or supervising the Research) must declare a conflict of interest.
- 6.3. Where a DSREC Member declares a conflict of interest, the DSREC will usually require that the Member withdraws from the discussion/review of the application to which the declaration relates. All conflict of interest declarations must be recorded by the DSREC.

7. DSREC Operations

7.1. Type of Review

The DSREC requires that all Human Research proposals be subject to full review by the DSREC.

7.2. Submission Process

7.2.1. Human Research proposals should only be submitted to the DSREC for ethical review where it is certain that the Research will go ahead (subject to all relevant approvals being obtained). If the Research is dependent on a successful funding application, the proposal should not normally be submitted to the DSREC until confirmation of funding is obtained. However, if a funder requires a statement from the DSREC prior to making a decision about the success of the funding application, or where the Research must start immediately after the funding has been obtained, the DSREC will consider the proposal.

- 7.2.2. Prior to submission to the DSREC, Researchers must ensure that the Human Research proposal has been subject to appropriate scientific/peer review. It is not the role of the DSREC to perform this type of review.
- 7.2.3. The Chief/Principal Investigator must follow the steps below in order to obtain ethical review from the DSREC:
- Discuss the Human Research proposal with any co-investigators and/or Supervisors (for student research projects, or where otherwise applicable) including the ethical issues associated with the research project and what action will be proposed to the DSREC to address such issues.
 - Complete the relevant DSREC Application Form. For student research projects, the Supervisor will also be required to approve the Form.
 - Complete, collate and append all necessary supporting documentation as listed in the DSREC Application Form. This will usually include the proposal/protocol (or a clear description of the Research), all participant-facing documents (including recruitment documents, information sheets, consent forms, questionnaires). The Chief/Principal Investigator must pay particular attention to relevant Cardiff University policies, procedures and guidance and any local/discipline specific guidance on research ethics prior to finalising any proposed research project documents. A list of useful resources is contained at **Appendix 2**.
 - Submit the DSREC Application Form and all supporting documents as follows:

THREE copies of this form, your proposal, information, consent sheet, and (debrief sheet if any) should be submitted to Beverley Jones, Secretary, Dental School's Research Ethics Committee, Rm128, First Floor, Dental School, Heath Park, Cardiff - Email: jonesB5@cardiff.ac.uk.

Please ensure that all documentation contain a footnote, a version number and date.

E-MAIL APPLICATIONS IN THE ABSENCE OF HARD COPIES CANNOT BE ACCEPTED.

7.3. Frequency, Format and Timing of DSREC Meetings

- 7.3.1. The DSREC will convene monthly to consider applications submitted for ethical review. The monthly meetings will be time-tabled in advance and published. In order to be considered at the next meeting, applications for ethical review must be received at least 10 working days in advance of the meeting date.
- 7.3.2. Whilst the DSREC will always aim to meet in person to discuss applications, the DSREC may convene to consider and discuss applications electronically (through correspondence) or via a conference call. This will be at the discretion of the Chair of the DSREC and may be utilised where the application is deemed unproblematic or where the Chair otherwise considers it appropriate for an application to be considered outside of a meeting.
- 7.3.3. The DSREC does not normally invite the Chief/Principal Investigator to attend/take part in the DSREC's discussion of an application for ethical review.

However, the DSREC may do so in exceptional cases where it considers that such attendance would assist the DSREC.

- 7.3.4. Where an application for ethical review is received late (i.e. outside of the timescales indicated above) the application will not be considered until the next meeting of the DSREC, save in the most exceptional circumstances. Delay in starting the Research will not normally be accepted as an exceptional circumstance.

7.4. Review of Applications

- 7.4.1. To enable the DSREC to reach a decision about a Human Research proposal submitted for ethical review, the DSREC will consider relevant policies, procedures and guidance issued by Cardiff University, alongside any guidelines of relevant professional bodies, funders and organisations in the research discipline.
- 7.4.2. **The DSREC will reach a decision about the research proposal based on the information provided by the Chief/Principal Investigator. The Chief/Principal Investigator must ensure that all relevant information is provided to the DSREC and that the information provided is accurate.**
- 7.4.3. All DSREC Members will receive a copy of the application to consider, prior to the review meeting.
- 7.4.4. It is normally expected that the DSREC will reach a consensus in its decision-making. Where disagreement remains, decisions of the DSREC will be made by a majority vote, with the Chair having a casting vote.

7.5. Outcome of Review

Within 5 working days of the review meeting/consideration of the ethical review application, the DSREC may:

- 7.5.1. issue an 'Ethical Opinion' to the Chief/Principal Investigator;
- 7.5.2. defer consideration of the application, where significant further information is required (in such cases, the DSREC will confirm to the Chief/Principal Investigator what additional information is required, the deadline for the provision of such information, and a proposed timescale for DSREC review (which may be at the next scheduled DSREC meeting)); or
- 7.5.3. in exceptional cases, refer the application to URIEC in accordance with paragraph 7.7.

In the majority of cases the DSREC will issue one of the following Ethical Opinions to the Chief/Principal Investigator:

- 7.5.4. Favourable Opinion (no conditions). The DSREC does not require any changes to the Human Research proposal and the Researcher may proceed, provided no other approvals are outstanding. Authorisation to proceed is granted on the basis that the research project will proceed **exactly** as stated on the application for ethical review and in accordance with the research project documents reviewed by the DSREC.
- 7.5.5. Favourable Opinion (with conditions). The DSREC will detail the conditions of the favourable opinion in the response letter. The Researcher may only proceed once all conditions have been met, but is not required to revert to the DSREC to obtain a subsequent review (although the Researcher must notify the DSREC once all conditions have been met and provide copies of any revised documents).

- 7.5.6. Provisional Opinion. The DSREC will detail the conditions of the provisional opinion in the response letter. The Researcher must revert to the DSREC with evidence that all conditions have been met. The DSREC will nominate Member(s) to review the evidence submitted. If satisfactory, a favourable opinion letter will be issued by the DSREC in order that the Researcher may proceed, provided no other approvals are outstanding.
- 7.5.7. Unfavourable Opinion. The DSREC rejects the application. Detailed feedback will be issued to the Researcher. The Research cannot commence until a favourable opinion has been obtained.

7.6. Review of Amendments

- 7.6.1. Researchers are ultimately responsible for ensuring that all ethical issues arising from their research project are kept under regular review.
- 7.6.2. Researchers must inform the DSREC of any unexpected ethical issues or unexpected adverse events that arise during the research project.
- 7.6.3. The DSREC recognises that Researchers may need to amend their proposal and/or participant-facing documents during the lifecycle of a research project. Dependent on the nature and scale of the amendments (namely whether the amendments are 'substantial' or 'non-substantial'), the DSREC may be required to review the proposed amendments before they are implemented. The current review procedure adopted by the DSREC is set out below.

7.7. Substantial Amendments

- 7.7.1 Any substantial amendments to documents previously reviewed by the DSREC must be submitted to the DSREC (see 7.2.3) for consideration and cannot be implemented until the DSREC has confirmed it is satisfied with the proposed amendments.
- 7.7.2 For the purposes of the above, 'substantial' includes (but is not limited to):
- changes to any participant-facing documentation where such changes are likely to have an impact on the safety of participants or the nature of their involvement in the research project;
 - changes to the experimental procedures, the procedures undertaken by participants, or uses of the material/data;
 - change to the Chief/Principal Investigator;
 - a temporary halt of the research project to protect participants from harm, and the planned restart of the research project following the temporary halt;
 - other significant changes to research project documentation or the proposal submitted to the DSREC.
- 7.7.3 Proposed substantial amendments will be reviewed by the DSREC Chair (or DSREC Committee) and the outcome of the review notified to the Chief/Principal Investigator as soon as possible.

7.8. Non-substantial Amendments

- 7.8.1 Researchers may implement non-substantial amendments to documents previously reviewed by the DSREC. However, the DSREC must be notified of such changes (via email to DSREC Chair and Beverley Jones, Secretary; **Email: jonesB5@cardiff.ac.uk**), to enable the DSREC to update its records.
- 7.8.2 The following are examples of non-substantial amendments:

- minor changes to the research proposal or other research project documents such as the correction of errors and updating contact details;
- changes/additions to the wider research team (not including a change to the Chief/Principal Investigator);
- changes in funding arrangements;
- changes in documentation used by the research team for recording information about the research project data;
- changes in any logistical arrangements; or extension of the research project beyond the period specified in the application to the DSREC.
-

7.9 Referrals and Appeals

7.9.1 Where the DSREC is unable to satisfactorily resolve a query/issue that arises during the review of a Human Research proposal, it may refer the matter to URIEC for advice or guidance. Referrals must be made by the DSREC via the Head of School. URIEC will expect to receive a summary of the query/issue arising and may invite members of the School to a meeting to discuss the issue. The advice or guidance provided by URIEC will be recorded in writing and issued to the DSREC via the Head of School. The DSREC remains responsible for making a decision on the Human Research proposal and for notifying the Researchers of the progress of the application and the outcome of the review.

7.9.2 If a Researcher is dissatisfied with a decision made by a DSREC, this should be discussed with the Schools Ethics Officer in the first instance. If discussion is unable to resolve the issue satisfactorily, an appeal against the decision of the DSREC may be made to URIEC via the DSREC and the Head of School. However, it should be noted that URIEC will not normally interfere with a DSREC decision. URIEC is concerned only with the general principles of natural justice, reasonableness and fairness of the decision made by the DSREC.

8. **What research does DSREC cover?**

Majority of research involving humans conducted with the School Dentistry will be deemed "Clinical-research" and as such is subject to rules for ethical approval laid down by the National Research Ethics Service (NRES). Therefore, any research involving humans within the following categories fall outside the remit of the DSREC:

1. patients and users of the NHS. This is intended to mean all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions.
2. individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above;
3. access to data, organs or other bodily material of past and present NHS patients;
4. fetal material and IVF involving NHS patients;
5. the recently dead in NHS premises;
6. the use of, or potential access to, NHS premises or facilities;

All research in the above categories must receive ethical approval from the appropriate NHS Local / Multi-centre Research Ethics Committee (LREC / MREC).

In addition, studies which:

- are defined as clinical trials by the Medicine for Human Use (Clinical Trials) Regulations Act 2004
- involve patients who lack or will potentially lack mental capacity as defined in the Mental Capacity Act 2005

also require review via the NHS LREC/MREC mechanism.

However, you may be conducting **non-clinical research**, which involves healthy volunteers. Research may also be undertaken on tissue or fluid samples taken from healthy volunteers. Surveys and questionnaires on issues such as lifestyle, housing and working environments, attitudes and preferences may also form part or the whole of research projects.

Undergraduate or postgraduate students may undertake research as part of their degree work. It may also be undertaken by members of staff either as part of individual or team research work within the University or as externally contracted or funded work.

Such research, which falls within the NHS Ethical approval scheme, should be submitted to the School Research Ethics Committee for approval.

8.1. Research falling within the UK Policy Framework for Health and Social Care Research

8.2.1 All studies that fall within the above framework require Sponsorship from the University's Research Governance Team (Research and Innovation Services). Sponsorship should ideally be obtained before a proposal is submitted to the DSREC for review. In no circumstances should the research project commence before Sponsorship has been obtained, alongside any relevant external approvals associated with the Sponsorship process.

8.2.2 Chief/Principal Investigators must apply for Sponsorship using the University's Advanced Project Information Proforma. Further information is available [here](#)¹.

8.2. Security-sensitive Research

8.2.1. Research falling within the scope of the Prevent Duty, namely research involving terrorism, extremism and/or radicalisation (or research involving access to materials of such a nature) must be registered with the University in accordance with the Security-sensitive Research Policy.

8.3. Research involving the use of Social Media Data (or similar internet-based data)

8.3.1. The DSREC will consider all research proposals falling within this category if the data being accessed, collected or used by researchers comprises Human Data.

8.3.2. The DSREC recognises that Human Data obtained through social media or similar platforms can lawfully be used for research purposes without explicit consent, provided certain conditions are met. However, there are still important

¹ Student link: <https://intranet.cardiff.ac.uk/students/study/postgraduate-research-support/conducting-research-in-the-nhs/applying-for-sponsorship>

ethical matters to consider whenever a researcher is proposing to use such data for research purposes.

8.3.3. The Legal Position

Personal Data obtained through social media or similar platforms can lawfully be used for research purposes without explicit consent, where:

- the data has been 'manifestly made public by the data subject', as opposed to being made public by someone else;
- the data is not being used to make decisions about individuals;
- the use of the data would not impinge on the rights and freedoms of the individuals;
- the use of the data would not cause substantial damage/distress to the individuals;
- data minimisation techniques are employed so that only relevant information necessary for the research is captured and anonymisation takes place prior to publication; and
- the Researcher complies with the general data protection principles contained within the General Data Protection Regulation. See Cardiff University's GDPR Guidance for Researchers for further details.

Anonymised Human Data obtained through social media or similar platforms (i.e. where the data being accessed or collected relates to humans (or was obtained from humans) but contains no identifying information) is not subject to data protection legislation, and therefore can be used lawfully for research purposes.

8.3.4. The Ethical Position

In addition to ensuring the relevant conditions for lawful use are satisfied (as set out above), researchers must consider (and the DSREC will consider) the ethical implications of using the data for research purposes. Some relevant ethical questions to consider are:

- whether the information is truly 'public'. For example, if a researcher obtains information from a closed social media group/page or from a forum only available to certain users, the individual to which the data relates is unlikely to expect that the information will be used for another purpose. The terms and conditions of the internet provider may provide a useful starting point in terms of what content is considered 'public';
- the extent to which anonymity can truly be achieved. For example, if a researcher is proposing to use direct quotations in a research publication, the individual from which the quote was obtained may be easily ascertainable; and
- whether the information being accessed/used for research purposes is sensitive (which may increase the changes of harm/distress).

There are various frameworks available that address the ethical considerations of using social media/internet data in further detail. Whilst many of these were drafted prior to the introduction of the General Data Protection Regulation, they still provide a useful starting point for researchers and DSREC. Examples include:

- 'Social Media Research: A Guide to Ethics', ESRC and the University of Aberdeen
- 'Internet-mediated research', UK Research Integrity Office
- 'Internet-Based Research', University of Oxford

9. DSREC Governance

9.1. Record keeping

9.1.1. The School Ethics Officer (or a delegated nominee) will keep an accurate record of every DSREC meeting/deliberation. This must include details of:

- the names of those in attendance (where a meeting);
- any conflicts of interest declared;
- a summary of the matters discussed; and
- a report of the decisions made.

9.1.2. The School Ethics Officer (or a delegated nominee) will maintain a record of all applications submitted to the DSREC and the associated outcomes. The record will include details of (this list is not exhaustive):

- The research project (including title, start date, anticipated and actual end date)
- The Chief/Principal Investigator
- Whether the proposal was subject to full or proportionate review
- The application review date, the identity of the reviewers, and the outcome
- Any substantial amendments considered (including the review date, the identity of the reviewers, and the outcome)
- Any non-substantial amendments notified to the DSREC

9.1.3. The DSREC will ensure that all records are stored securely and that access is granted to the individuals responsible for maintaining the records.

9.2. Monitoring

9.2.1. The School Ethics Officer is responsible for ensuring that appropriate measures are in place to monitor the progress of studies that have received a favourable opinion.

9.2.2. When considering an application for ethical review, the DSREC will determine what form of monitoring is required for the research project and will confirm this to the Chief/Principal Investigator within the ethical opinion response letter. The form of monitoring required will depend on the type of research project and the risk involved. Consideration will be given to the use of:

- End of project reports;
- Annual reports;
- Periodic reports from and/or visits to the Chief/Principal Investigator;
- Oral updates to the DSREC (by the Chief/Principal Investigator);
- Establishing a project-specific monitoring provision.

9.3. Audit

In order to assess its performance against the standards contained in these Procedures and the Ethics Policy, the DSREC may audit its activity from time to time. This may include conducting a review of a sample of applications previously reviewed by the Committee and may include auditing the evidence provided by Researchers where ethical review was conducted by another university or institution.

9.4. Closure/reporting

For all studies reviewed by the DSREC, the DSREC requires notification from the Chief/Principal Investigator when the research project has ended. This notification should be made within three months of research project completion.

10. Contact/Queries

All queries regarding the procedures or operation of the DSREC should be directed to DSREC Chair, Professor Vaseekaran Sivarajasingam (Email: sivarajasingam@cardiff.ac.uk) or DSREC Secretary, Mrs Beverley Jones (Email: jonesb5@cardiff.ac.uk)

Appendix 1

Chair – Professor V Sivarajasingam

Vice Chair – Dr I Johnson

Academic Members – Dr C Emanuel

Dr D Farnell

Dr K Hill

Mr M Langlely

Dr X Wei

External – Dr A Sydor

Lay Members – Dr F Morgan

Secretary - Mrs B Jones

Appendix 2

Useful resources for DSREC Researchers

General/Central Cardiff University policies and guidance

- Cardiff University Policy on the Ethical Conduct of Research involving Human Participants, Human Material or Human Data
- [Research Integrity and Governance Code of Practice](#)

NOTE: Both above documents refer Researchers to a range of other relevant policies, procedures and guidance relating to Research Ethics and Integrity.